510(k) Summary K061467

Sponsor: Alcavis International
8322 Helgerman Court
Gaithersburg, MD 20877

FEB 15 2007

Contact Person: Gary J. Mishkin
Vice President, Research and Development
Tele: (301) 330-7597
Fax: (301) 330-6432

Date Prepared: May 4, 2006

Device Name: Proprietary Name: ExSept WC
Common Name: Wound Cleanser
Classification Name: Liquid Bandage (21CFR 880.5090)

Predicate Devices: Allclenz Wound Cleaner, K965120
CarraKlenz Wound Cleanser, K022670
Dermacyn Wound Cleanser, K042729

Device Description: ExSept WC is a clear to slight yellow, slight chlorine odor, solution which is intended for the mechanical cleansing of debris and foreign material from exudating/dirty epidermal and dermal wounds. It is supplied in a 200 ml pump-spray and a 100 ml, 250 ml, and 500 ml pour white, opaque, bottles. ExSept WC has a shelf-life of 30 months.

Indications for Use: For debridement and the removal of foreign material and debris from exudating and/or dirty wounds, abrasions and minor irritations, cuts, exit sites, and intact skin.

Intended Use: For the flushing and mechanical cleansing of dirt and debris from epidermal and dermal wounds, post-surgical wounds, abrasions and minor irritations, cuts, exit sites, other minor wounds, and intact skin,

Substantial Equivalence: ExSept WC is substantially equivalent in the cleansing functions and intended uses to the predicate devices Allclenz, CarraKlenz, and Dermacyn. All predicate devices use a flushing action to remove foreign material and other debris from the wounds and surrounding skin.

Testing: Non-clinical in-vitro testing was performed to demonstrate the biocompatibility of ExSept WC for it's intended purpose and to support the 30 month shelf-life for the product.

Conclusion: Based upon the information in the 510(k) submission, ExSept WC will perform as intended as a wound cleanser, and is substantially equivalent in its actions and functions as the marketed devices Allclenz, CarraKlenz, and Dermacyn.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alcavis International, Inc.
% Mr. Gary J. Mishkin, M.S.
VP, Research and Development
8322 Helgerman Court
Gaithersburg, Maryland 20877

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Re: K061467
Trade/Device Name: ExSept WC Wound Cleanser
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 22, 2006
Received: December 26, 2006

Dear Mr. Mishkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061467

Indications for Use

510(k) Number (if known):

Device Name: ExSept WC Wound Cleanser

Indications For Use:

For debridement and the removal of foreign material and debris from exudating and/or dirty wounds, abrasions and minor irritations, cuts, exit sites, and intact skin.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061467